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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,199	06/13/2001	Cornelis Theodorus Verrips	F7544(V)	6098

201 7590 08/21/2008  
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EXAMINER
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CHAWLA, JYOTI

ART UNIT	PAPER NUMBER
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1794

MAIL DATE	DELIVERY MODE
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08/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/880,199	<b>Applicant(s)</b> VERRIPS, CORNELIS THEODORUS	
	<b>Examiner</b> JYOTI CHAWLA	<b>Art Unit</b> 1794	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6, 12-14, 19, 21-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 12-14, 19, 21-25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/2008</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/23/2008 has been entered. Claims submitted by the applicant dated 3/20/2008 will be regarded as the outstanding claims and will be examined in the present office action. Claims 28 and 29 have been added. Claims 6, 12-14, 19-25 and 27-29 are pending and examined.

### ***Minor Informality***

The applicant is requested to furnish dates of Publication of all the Non-patent Literature by providing the Title sheet and the printing or copyright date wherever missing in the documents provided to the office in the current application.

### ***Claim Rejections - 35 USC § 112(Second paragraph)***

Rejection of claims 24-25, 27, 6, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite the recitation of "no substantial fermentation of the food product by said Lactobacillus bacteria will take place by said non-viable bacteria", has been withdrawn based on applicant's remarks filed February 21, 2008.

### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(i) Claims 6, 24-25, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Meister et al. (US PAT 6,010,725). Meister et al. is herein incorporated as cited at page 6 of the February 25, 2004 Office action.

Regarding claims 24 and 29, Meister teaches a process for spray-drying a composition of microorganisms, including *Lactobacillus*, wherein the process is adjusted so as to obtain survival of at least 1% of the microorganisms after drying (col. 2). A culture of microorganisms is mixed with a liquid preparation of a food composition, such as milk, or one from meat, fruits or vegetables (col. 4), which is subsequently spray-dried to form a dried food composition containing amounts of both viable and non-viable bacteria. As an example, at column 5, it is stated that the liquid mixture of the process may initially contain  $10^8$  cfu /g active bacteria, but after drying, only contains  $10^6$  cfu /g active bacteria. The remainder are rendered non-viable (not active and not alive). The spray-drying process employs temperatures of greater than 200°C, which includes the pasteurization temperature range. Further it is noted that the recitation of the bacterial property in claim 25, actually amounts to a “product by process”, within the process claim 24. Such a recitation of the method of making the product utilized within the process claim (claim 24), must result in a structural difference between the claimed invention starting product and the prior art starting product in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the claimed process and would reasonably meet the claimed property limitations, which it does, then the claim is anticipated as stated. In other words, a bacteria pasteurized in line for 30 seconds at 72°C would not appear to patentably differ from those disclosed in the reference.

Regarding applicant's argument regarding Meister not teaching non-viable bacteria as recited in the claim (Remarks, filed February 2008, pages 6-7), applicant is referred to response to arguments of the previous office actions where it was clarified that applicant's allegation has not been found persuasive. In response, reference is made to page 5 of the instant specification, which defines the term "non-viable *Lactobacillus* bacteria" as those "of which substantially all or all bacteria are incapable of growing under the appropriate growing conditions of said *Lactobacillus* strain." The Meister reference, again, discloses a process and resulting food product which yields "at least 1% survival of the microorganisms" after drying. See col. 5, lines 55-61, where the initial composition contains more than  $10^8$  cfu/g ( $10^{10}$  cfu/ 100g), and after drying (i.e. pasteurization or heat treatment) "more than  $10^6$  cfu/g [ $10^8$  cfu/ 100g] are still active and alive." This amounts to a mere 1% of viable bacteria present in the composition, which also means that 99% are non-viable. This reads upon the specification-defined term of "non-viable *Lactobacillus* bacteria" where "substantially all or all bacteria are incapable of growing under the appropriate growing conditions of said *Lactobacillus* strain" (emphasis added).

Thus, Meister teaches of a method of producing a food product as recited by independent claims 24 and 29.

(ii) Claims 6, 12-14, 19, 21-22, 24 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Klaver et al. (US 5409718).

Klaver et al, hereinafter Klaver, teaches a dairy based food product comprising probiotic *Lactobacillus* bacteria, which have been rendered non-viable (Abstract). Klaver teaches addition of culture of *Lactobacillus* to the milk and culture it. It is known that all active bacterial cultures contain some non-viable bacteria, thus the reference teaches addition of active and non-viable *Lactobacillus* to the milk. Klaver further teaches that the fully-grown culture of *Lactobacillus* is heated in such a way that the all bacteria present are destroyed (i.e., rendered non-viable). Klaver also teaches that it is important that the

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culture be heated such that no living bacteria survive and also little or no enzymatic activity occurs after the heat treatment. Klaver further teaches that the heating time and temperature are chosen to have the same effect as heating for 85°C for 1 minute (Column 3, lines 15-35). Pasteurization is a well-known heat treatment aimed at inactivating enzymes and destroying 99-99.9% bacterial cells, and Klaver teaches the heat treatment of the food product containing the lactobacillus in order to destroy all lactobacillus (i.e., rendering non-viable) such that little or no enzyme activity can take place. Although Klaver does not call the heat treatment step as pasteurization, however, the reference does teach a heat treatment step that leads to the same results as expected by pasteurization, i.e., all bacteria are destroyed and no enzymatic activity which would lead to no substantial fermentation by the lactobacilli after the heat treatment (Column 3). Thus Klaver reference teaches heat treatment, i.e., pasteurization and also teaches that no substantial fermentation by the lactobacillus will take place as recited in the claims 14 and 28.

Further it is noted that the recitation of the bacterial property in claim 25, actually amounts to a “product by process”, within the process claim 24. Such a recitation of the method of making the product utilized within the process claim (claim 24), must result in a structural difference between the claimed invention starting product and the prior art starting product in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the claimed process and would reasonably meet the claimed property limitations, which it does, then the claim is anticipated as stated. In other words, a bacteria pasteurized in line for 30 seconds at 72°C would not appear to patentably differ from those disclosed in the Klaver reference.

Regarding claims 12 and 13, Klaver teaches heat treatment of food with lactobacillus in a way that all the bacteria present are destroyed (i.e., rendered non-viable) by the heat treatment (i.e., pasteurization as it is noted that pasteurization is a heat treatment to curb or reduce microbial activity and preserve food)(Column 3, lines 25-35). Thus

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Klaver teaches of food product wherein a ratio of non-viable to viable bacteria more than 5:1 and 10:1 as claimed instantly.

Regarding claim 19 and 22, Klaver teaches of a dairy based food product that can be consumed as a healthy snack as recited by the applicant (Abstract).

Regarding claims 24 and 29, Klaver teaches a food product comprising Lactobacillus bacteria (i.e., probiotic) and renders them non-viable by heat treatment to destroy all the bacteria after the addition of bacteria to the milk as discussed above regarding claim 14. Since the reference teaches of heat-treating the Lactobacillus containing food to destroy all the bacteria, and have little or no enzymatic activity, therefore the reference does teach that no substantial fermentation would take place by the non-viable bacteria as recited in claim 24. Also see the rejection above regarding claim 14.

Regarding claim 6 and 21, Klaver teaches of a dairy based food product that can be consumed as a healthy snack as recited by the applicant.

(iii) Claims 12-14, 24-25, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter (EP 0279618), already of record.

Porter teaches of probiotic product comprising killed, i.e., non-viable, non pathogenic microbial cells in a liquid culture, where the microbial cells are killed autoclaving or boiling (Page 2, lines 17-28). Porter further states that "the killed cells can be dried and included in an animal feed" (Page 2, line38) which can be administered to chicks, ruminants and monogastric animals (Page4, lines 60-62). Porter also discloses that "stability is improved over other probiotics as no live bacteria are present". Porter also teaches that dried or liquid products can be manufactured wherein the products have useful nutritional properties (Page 3, lines 1-6). Porter also teaches of Lactobacillus as part of the non-viable bacterial culture (Page3, lines 36-38 and 52-59). Since porter teaches of addition of killed or non-viable bacteria to the animal feed or food, therefore

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no substantial fermentation of the feed will take place by said killed lactobacillus bacteria. Regarding the step of pasteurization, as recited in claims 14, 24, 25, 28-29, Porter further teaches that the heating time and temperature are chosen to have the same effect as heating for 121<sup>0</sup>C for 20 minute to autoclave (Page 3, line 52), which would be able to kill the microorganisms and preserve the composition comprising the non-viable bacteria, as is instantly claimed. Pasteurization is a well-known heat treatment aimed at inactivating enzymes and destroying 99-99.9% bacterial cells, and Porter teaches the heat treatment of the food product containing the lactobacillus in order to destroy all lactobacillus (i.e., killing the cells or rendering non-viable) such no enzyme activity can take place. Although Porter does not call the heat treatment step as pasteurization, however, the reference does teach a heat treatment step that leads to the same results as expected by pasteurization, i.e., all bacteria are destroyed and no enzymatic activity which would lead to no substantial fermentation by the lactobacilli after the heat treatment (Page 3). Thus, Porter reference teaches heat treatment, i.e., pasteurization and also teaches that no substantial fermentation by the lactobacillus will take place as recited in the claims 14, 24, 28 and 29.

Regarding claims 12-13, porter teaches of killing all the bacterial cells before addition to any food or feed product (Pages 2 and 3), thereby teaching the ratio of non-viable to viable bacteria higher than 5:1 and 10:1 , as instantly claimed.

Further, it is noted that the recitation of the pasteurization actually amounts to a “product by process”, within the process claim 24, such a recitation of the method of making the product utilized within the process claim (claim 24), must result in a structural difference between the claimed invention starting product and the prior art starting product in order to patentably distinguish the claimed invention from the prior art. The Porter reference teaches of heating for 20 minutes at 121 <sup>0</sup>C, which is capable of killing all the microbes, i.e., render all the bacteria non-viable. If the prior art structure is capable of performing the claimed process and would reasonably meet the claimed property limitations, which it does, then the claim is anticipated as stated. In other words, a bacteria pasteurized in



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line for 30 seconds at 72°C would not appear to patentably differ from those disclosed in the Porter reference.

Thus, Porter anticipates a method of making a food product as recited in claims 12-14, 24-25 and 28-29.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(A) Claims 6 and 21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meister (US PAT 6,010,725), in view of Froseth et al. (US PAT 6,592,915).

Note that Froseth et al. qualifies as prior art under 35 U.S.C. 102(e) and thus 35 U.S.C. 103(a).

Meister et al. discloses that a culture of microorganisms is mixed with a liquid preparation of a food composition, such as milk, or one from meat, fruits or vegetables (col. 4), which is subsequently spray-dried to form a dried food composition containing amounts of both viable and non-viable bacteria. Froseth et al. disclose the production of layered cereal bars containing ready-to-eat (RTE) cereal, wherein "the basic physical

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composition of the cereal bar is that of a 'sandwich' composed of two cereal layers with a visible center or middle layer, e.g., a creamy milk-filling layer." The bar may contain various components and additives, where it is stated that "additives further include nutrient and health additives such as vitamins, minerals, encapsulated biologically active components, nutraceuticals..., probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)... protein powders, powdered milk fractions, protein or satiety additives...and other similar health-enhancing additives"[underlining added]. The use of milk powder in the cereal bar is mentioned throughout Froseth (Column 4, lines 20-35).

Therefore, it is maintained that it would have been obvious for one of ordinary skill in the art to have utilized the known probiotic bacteria (*Lactobacillus*)-containing powdered milk preparation of Meister et al. within the layered cereal bar of Froseth et al., which contained a "milk-filling layer", and which specifically suggested the use of "probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)", "powdered milk fractions," "and other similar health-enhancing additives." It would not have involved an inventive step for one skilled in the art to have utilized this known preparation. Further, both compositions provide their stated and known contributions, and thus the combination of references reads upon the instantly-claimed invention.

(B) Claims 25 and 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klaver (US 5409718) in view of Dairy Science and Technology Handbook.

Klaver has been applied to claims 6, 12-14, 19, 21-22 and 24, 25 above.

Regarding claim 25, Klaver teaches of heat treatment of the milk containing lactobacillus culture in order to destroy the bacteria and inactivate enzymes as discussed above regarding claims 14 and 24. The reference further teaches of heating time and temperature that can be chosen to have the same effect as heating for 85<sup>0</sup>C for 1 minute (Column 3, lines 15-35) which would result in pasteurizing the food product and rendering the lactobacilli non-viable. Although Klaver does not refer to the heat treatment step as pasteurization, however, the reference does teach a heat treatment

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step that leads to the same results as expected by pasteurization, i.e., all bacteria are destroyed and no enzymatic activity which would lead to no substantial fermentation by the lactobacilli after the heat treatment. Pasteurization is a well-known heat treatment aimed at inactivating enzymes and destroying 99-99.9% bacterial cells. Furthermore, it has been known that pasteurizing a food for 30 seconds at 72<sup>0</sup>C is only one of several recommended time-temperature ranges at which the desired microbial destruction can be achieved. Pasteurization can be effectively performed at various other time-temperature ranges where, the time of exposure to elevated temperature is inversely proportional to the temperature of exposure, i.e., higher the temperature shorter exposure time required to achieve the similar results. Klaver reference teaches heating the lactobacillus milk culture for 85<sup>0</sup>C for 1 minute in order to render the lactobacilli non-viable and destroy the enzymes, (i.e., higher temperature and longer time than recited) (Column 3, lines 15-35), which will lead to at least the same level of bacterial non-viability and enzyme deactivation as expected by pasteurization for 30 seconds at 72<sup>0</sup>C, as recited in claim 25. Thus Klaver teaches a heat treatment to destroy the bacteria and enzymes as intended by the applicant and uses heat treatment to render the bacteria non-viable also as intended by the applicant. Furthermore, pasteurization is a well-known heat treatment aimed at inactivating enzymes and destroying 99-99.9% bacterial cells therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that Klaver reference teaches rendering the bacteria non-viable by heating just as well as by pasteurization step for 30 seconds at 72<sup>0</sup>C, as instantly claimed.

Regarding claim 27, Klaver teaches a food product containing non-viable lactobacilli as discussed above. The reference teaches the amount of lactobacilli added to milk to form the culture should be as customary in traditional preparation of yogurt. The reference further teaches addition of 0.025 to 5% of lactobacilli (Column 3, lines 15-35). The reference, however, does not teach the amount of non-viable bacteria in the food product in cells or CFU as recited by the applicant in claim 27.

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Dairy Science and Technology Handbook teaches inoculation for yogurt is generally done at the rate of 0.5 to 5% (page 26), as taught by Klaver. Dairy Science and Technology Handbook further teaches that the yogurt starter culture is added as a bulk starter containing  $10^8$  to  $10^9$  CFU/gram (page 23). Thus the bulk starter containing  $10^8$  to  $10^9$  CFU of bacteria /gram would fall in the range of 0.5-5% of bacterial cells added as culture. Klaver teaches the amount of bacteria as a percent of the medium inoculated in the same range as the Dairy Science and Technology Handbook, therefore, one of ordinary skill in the art at the time of the invention would have a reasonable expectation that Klaver also adds lactobacilli in the amount  $10^8$  to  $10^9$  CFU/gram, as taught by Dairy Science and Technology, which will fall applicant's recited range recited. Therefore, Klaver in view of Dairy Science and Technology Handbook teaches the amount of non-viable bacteria in food as recited in claim 27.

(C) Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaver (US 5409718), in view of Forseth (US PAT 6,592,915) as cited above.

Note that Froseth et al. qualifies as prior art under 35 U.S.C. 102(e) and thus 35 U.S.C. 103(a).

Klaver has been applied to claims 6, 12-14, 19, 21-22 and 24 above.

Froseth et al. disclose the production of layered cereal bars containing ready-to-eat (RTE) cereal, wherein "the basic physical composition of the cereal bar is that of a 'sandwich' composed of two cereal layers with a visible center or middle layer, e.g., a creamy milk-filling layer." The bar may contain various components and additives, where it is stated that "Additives further include nutrient and health additives such as vitamins, minerals, encapsulated biologically active components, nutraceuticals..., dietary supplements, anti-oxidants, fibers, inulin, calcium carbonate, probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus), energy additives, protein powders, powdered milk fractions, protein or satiety additives, herbs, aromatic substances, and other similar health-enhancing additives." [emphasis added]

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The use of milk powder in the cereal bar is mentioned throughout Froseth et al. Klaver teaches of a food product containing heat destroyed (i.e., non-viable) Lactobacilli which can be concentrated and dried by spray drying (Column 4, lines 12-20). Klaver also teaches milk as the culture medium for lactobacilli (Column 3, lines 15-35), thus the spray-dried composition containing non-viable lactobacilli would be a milk based composition. Klaver further teaches addition of the spray dried powder to milk for making other cultured foods (Column 4, lines 20-26). Thus, Klaver teaches that the powdered composition containing non-viable lactobacilli can be added to foods. Therefore, it would have been obvious for one of ordinary skill in the art to have utilized the known dried probiotic bacteria (*Lactobacillus*)-containing milk based food preparation of Klaver within the layered cereal bar of Froseth et al., which contained a “milk-filling layer”, and which specifically suggested the use of “probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)”, “powdered milk fractions,” “and other similar health-enhancing additives.” It would not have involved an inventive step for one skilled in the art to have utilized this known preparation. Thus, the combination of references reads upon the instantly-claimed invention.

(D) Claims 25 and 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (EP 0279618 A2) in view of Dairy Science and Technology Handbook.

Porter has been applied to claims 12-14, 24-25, 28 and 29 above.

Regarding claim 25, Porter teaches of heat treatment of milk based lactobacillus culture in order to destroy the bacteria and inactivate enzymes as discussed above regarding claims 14 and 24. Porter further teaches of heating time (20 minutes) and temperature (121 °C) and teaches that the heating method can be chosen to have the same effect as heating for 20 minutes at 121°C (Pages 2 and 3) which would result in the same effect of killing all the microbes in the culture as the applicant intends by pasteurizing the food product and rendering the lactobacilli non-viable. Although Porter does not refer to the heat treatment step as pasteurization, however, the reference does teach a

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heat treatment step that leads to the same results as expected by the step of pasteurization, i.e., all bacteria are destroyed and no enzymatic activity which would lead to no substantial fermentation by the lactobacilli after the heat treatment.

Pasteurization is a well-known heat treatment aimed at inactivating enzymes and destroying 99-99.9% bacterial cells. Furthermore, it has been known that pasteurizing a food for 30 seconds at 72<sup>0</sup>C is only one of several recommended time-temperature ranges at which the desired microbial destruction can be achieved. Pasteurization can be effectively performed at various other time-temperature ranges where, the time of exposure to elevated temperature is inversely proportional to the temperature of exposure, i.e., higher the temperature shorter exposure time required to achieve the similar results. Porter reference teaches heating the lactobacillus milk culture at 121<sup>0</sup>C for 20 minutes in order to render all the probiotic bacteria, including lactobacilli non-viable and destroy the enzymes, (i.e., higher temperature and longer time than recited) (Pages 2-3), which will lead to at least the same level of bacterial non-viability and enzyme deactivation as expected by pasteurization for 30 seconds at 72<sup>0</sup>C, as recited in claim 25. Thus Porter teaches a heat treatment to destroy the bacteria and enzymes as intended by the applicant and uses heat treatment to render the bacteria non-viable also as intended by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that Porter reference teaches rendering the bacteria non-viable by heating just as well as by pasteurization step for 30 seconds at 72<sup>0</sup>C, as instantly claimed.

Regarding claim 27, Porter teaches a food product containing non-viable lactobacilli as discussed above. The reference does not specify the amount of lactobacilli added, however teaches of addition of parts by weight per million parts by weight of food, i.e., parts per 10<sup>6</sup> parts of food. Thus the reference teaches of parts by weight 1 gram per 1000 Kg of food (Page 3, line 60 to page 4, line 3). The reference, however, does not teach the amount of non-viable bacteria in the food product in cells or CFU as recited by the applicant in claim 27.

Dairy Science and Technology Handbook teaches inoculation for yogurt is generally done at the rate of 0.5 to 5% (page 26), i.e., a food product as taught by Porter. Dairy

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Science and Technology Handbook further teaches that the yogurt starter culture is added as a bulk starter containing  $10^8$  to  $10^9$  CFU/gram (page 23). Thus the bulk starter containing  $10^8$  to  $10^9$  CFU of bacteria /gram would fall in the range suitable for a food product as taught by Dairy Science and Technology Handbook, therefore, one of ordinary skill in the art at the time of the invention would be motivated to add a similar or comparable amount of bacterial culture comprising lactobacilli (in the amount  $10^8$  to  $10^9$  CFU/gram), as taught by Dairy Science and Technology, at least in order to make a food product with adequate amount of bacterial cells to provide the desired level of nutritional benefit. Therefore, Porter in view of Dairy Science and Technology Handbook teaches the amount of non-viable bacteria in food as recited in claim 27.

(E) Claims 6, 19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (EP279618 A2), in view of Forseth (US PAT 6,592,915).

Note that Froseth et al. qualifies as prior art under 35 U.S.C. 102(e) and thus 35 U.S.C. 103(a).

Porter has been applied to claims 12-14, 24-25, 28 and 29 above.

Porter teaches on non-viable bacterial culture to be added to foods and feed. Porter also teaches that the food additive can be added to foods of monogastric animals (Page 4, lines 60-62). Porter does not specify the particular foods to which the probiotic non-viable bacterial culture can be added. However, probiotic bacterial cultures were known to be added to foods as recited in claims 6, 19, 21-23 at the time of the invention.

Froseth et al. disclose the production of layered cereal bars containing ready-to-eat (RTE) cereal, wherein "the basic physical composition of the cereal bar is that of a 'sandwich' composed of two cereal layers with a visible center or middle layer, e.g., a creamy milk-filling layer." The bar may contain various components and additives, where it is stated that "Additives further include nutrient and health additives such as vitamins, minerals, encapsulated biologically active components, nutraceuticals...,

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dietary supplements, anti-oxidants, fibers, inulin, calcium carbonate, probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus), energy additives, protein powders, powdered milk fractions, protein or satiety additives, herbs, aromatic substances, and other similar health-enhancing additives." [emphasis added]

The use of milk powder in the cereal bar is mentioned throughout Froseth et al.

Porter teaches of a food product containing heat destroyed (i.e., non-viable) Lactobacilli which can be concentrated and dried by autoclaving or other methods (Page 4, lines 52-60). Porter also teaches milk as the culture medium for lactobacilli (Column 3, lines 15-35), thus the dried composition containing non-viable lactobacilli can be a sweet or milk based composition. Porter further teaches addition of the spray dried powder to food for monogastrics and making other food products (Page 4). Thus, Porter teaches that the powdered composition containing non-viable lactobacilli can be added to foods.

Therefore, it would have been obvious for one of ordinary skill in the art to have utilized the known dried probiotic bacteria (*Lactobacillus*)-containing food preparation of Porter within the layered cereal bar of Froseth et al., which contained a "filling layer", and which specifically suggested the use of "probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)", "powdered fractions," "and other similar health-enhancing additives." It would not have involved an inventive step for one skilled in the art to have utilized this known preparation. Thus, the combination of references reads upon the instantly-claimed invention.

### ***Response to Arguments***

Applicants have not presented any new arguments and the last submission of arguments dated February 21, 2008 has been responded in the advisory actions dated 3/18/2008 and 4/8/2008.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Chawla whose telephone number is (571) 272-8212. The examiner can normally be reached on 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JC  
Examiner  
Art Unit 1761

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794

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